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20 *C. R. Bard, Inc. and*
21 *Bard Peripheral Vascular, Inc.*

13
14 **IN THE UNITED STATES DISTRICT COURT**
15 **FOR THE DISTRICT OF ARIZONA**

16 IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
17 Litigation

18 This Document Relates to:

19 CLAUDETTE Y. MEARS,

20 Plaintiff,

Case No. CV-15-1899-PHX-DGC

21 v.

22 C. R. BARD, INC., a New Jersey
23 Corporation; AND BARD PERIPHERAL
24 VASCULAR INC., an Arizona
Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

25 Defendants.

26 Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV")
27 (Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiff's
28 Complaint") of Plaintiff Claudette Y. Mears ("Plaintiff") as follows:

PARTIES

1. To the extent the allegations in Paragraph 1 of Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are denied. Defendants are without information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiff's Complaint.

2. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Pennsylvania. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants deny any remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.

3. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Pennsylvania, including this judicial district. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. Paragraph 4 of Plaintiff's Complaint does not include any factual allegations and, as a result, requires no response by Defendants. However, to the extent Paragraph 4 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

5. The allegations of Paragraph 5 of Plaintiff's Complaint are not directed to Bard or BPV, and, as a result, require no response by Defendants. However, to the extent Paragraph 5 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

6. The allegations of Paragraph 6 of Plaintiff's Complaint are not directed to Bard or BPV, and, as a result, require no response by Defendants. However, to the extent Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

8. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

9. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Middle District of Pennsylvania.

ALLEGATIONS

10. Defendants deny the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendants admit that Bard designed, manufactured, and sold a device named the G2® Filter. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 11 of Plaintiff's Complaint.

1 12. Defendants deny the allegations contained in Paragraph 12 of Plaintiff's
2 Complaint, including all sub-parts thereof.

3 13. Defendants lack knowledge or information sufficient to form a belief as to the
4 truth of the allegation regarding the time frame when inferior vena cava filters were first
5 introduced on the market or the identity of manufacturers of inferior vena cava filters.
6 Defendants deny any remaining allegations of Paragraph 13 of Plaintiff's Complaint.

7 14. Defendants admit that inferior vena cava filters are intended to prevent injury or
8 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
9 that inferior vena cava filters may be designed for permanent placement, temporary
10 placement, or both. Defendants deny any remaining allegations of Paragraph 14 of Plaintiff's
11 Complaint.

12 15. Defendants admit that the inferior vena cava is a large vein that receives blood
13 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
14 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
15 human health, including sometimes death. Defendants deny any remaining allegations of
16 Paragraph 15 of Plaintiff's Complaint.

17 16. Defendants admit that certain people are at an increased risk for the
18 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
19 to form a belief as to the truth of the allegations as stated regarding the various risk factors
20 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
21 deny them. Defendants deny any remaining allegations of Paragraph 16 of Plaintiff's
22 Complaint.

23 17. Defendants admit that patients at a high risk for developing deep vein
24 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
25 including but not limited to the medications listed in Paragraph 17 of Plaintiff's Complaint.
26 Defendants further admit that inferior vena cava filters may also be used to treat patients who
27 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants

1 lack knowledge or information sufficient to form a belief as to the truth of any remaining
2 allegations contained in Paragraph 17 of Plaintiff's Complaint and, on that basis, deny them.

3 18. Defendants lack knowledge or information or information sufficient to form a
4 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
5 were first introduced on the market. Defendants also lack knowledge or information sufficient
6 to form a belief as to the truth of the allegation regarding the time frame when optional or
7 retrievable filters came to be marketed or the other allegations regarding optional or
8 retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
9 and G2® Filters were cleared by the FDA for optional use as retrievable inferior vena cava
10 filters. Defendants deny any remaining allegations contained in Paragraph 18 of Plaintiff's
11 Complaint.

12 19. Defendants admit that the Recovery® Filter was cleared by the FDA for
13 permanent placement on November 27, 2002, pursuant to an application submitted under
14 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the
15 requirements of Section 510(k) contained in Footnote 1 are legal conclusions of law to which
16 no answer is required. Defendants deny any remaining allegations contained in Paragraph 19
17 of Plaintiff's Complaint, including any allegations contained in Footnote 1.

18 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
19 retrievable placement on July 25, 2003, pursuant to an application submitted under Section
20 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations
21 contained in Paragraph 20 of Plaintiff's Complaint.

22 21. Defendants deny the allegations contained in Paragraph 21 of Plaintiff's
23 Complaint.

24 22. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
25 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
26 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
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1 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
2 allegations contained in Paragraph 22 of Plaintiff's Complaint.

3 23. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
4 manufacture of the Recovery Filter and further admit that Nitinol contains shape memory.
5 However, to the extent Paragraph 23 purports to cast liability either directly or indirectly
6 upon Defendants, said Paragraph is expressly denied.

7 24. Defendants admit that the Recovery® Filter was designed to be inserted
8 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
9 delivered via an introducer sheath, which is included in the delivery system for the device.
10 Defendants are without knowledge or information sufficient to form a belief as to the truth of
11 the allegations contained in Paragraph 24 of Plaintiff's Complaint regarding the typical
12 practices of physicians, including physician methods for determining successful implantation
13 of the Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any
14 remaining allegations of Paragraph 24 of Plaintiff's Complaint.

15 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiff's
16 Complaint, including any allegations contained in Footnote 2.

17 26. Defendants deny the allegations contained in Paragraph 26 of Plaintiff's
18 Complaint.

19 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
20 Complaint.

21 28. Defendants admit that there are various well-documented complications that
22 may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava
23 filter. Defendants further admit that it is well documented that many instances of filter
24 fracture, perforation, and and/or migration result in no complications whatsoever but, rather,
25 are completely asymptomatic. By way of further response, Bard states that there are incidents
26 related to the occurrence of known complications associated with every manufacturer of
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1 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 28 of
2 Plaintiff's Complaint, including all sub-parts thereof.

3 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
4 Complaint.

5 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiff's
6 Complaint.

7 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's
8 Complaint.

9 32. Defendants admit that there are various well-documented complications that
10 may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena
11 cava filter. Defendants further admit that it is well documented that many instances of filter
12 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
13 are completely asymptomatic. By way of further response, Bard states that there are incidents
14 related to the occurrence of known complications associated with every manufacturer of
15 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 32 of
16 Plaintiff's Complaint, including all sub-parts thereof.

17 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
18 Complaint.

19 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
20 Complaint.

21 35. Defendants admit that, as part of their continuing efforts to constantly evaluate
22 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
23 continually striving to improve the life-saving performance of those devices. The G2® Filter
24 was developed in furtherance of those efforts. Defendants deny the remaining allegations
25 contained in Paragraph 35 of Plaintiff's Complaint.

26 36. Defendants admit the G2® Filter System was cleared by the United States Food
27 and Drug Administration pursuant to an application submitted under Section 510(k) of the
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1 Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared
2 by the FDA for permanent use. Defendants further admit that the G2® Filter was
3 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
4 Defendants deny any remaining allegations contained in Paragraph 36 of Plaintiff's
5 Complaint.

6 37. Defendants admit that, as part of their continuing efforts to constantly evaluate
7 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
8 continually striving to improve the life-saving performance of those devices. The G2® Filter
9 was developed in furtherance of those efforts. Defendants deny any remaining allegations of
10 Paragraph 37 of Plaintiff's Complaint.

11 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
12 Complaint.

13 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's
14 Complaint.

15 40. Defendants admit that there are various well-documented complications that
16 may occur as a result of the fracture, perforation, tilt, and/or migration of any inferior vena
17 cava filter. Defendants further admit that it is well documented that many instances of filter
18 fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather,
19 are completely asymptomatic. By way of further response, Bard states that there are incidents
20 related to the occurrence of known complications associated with every manufacturer of
21 inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 40 of
22 Plaintiff's Complaint, including all sub-parts thereof.

23 41. Defendants admit that there are various well-documented complications that
24 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
25 cava filter. Bard states that there are incidents related to the occurrence of known
26 complications associated with every manufacturer of inferior vena cava filters. By way of
27 further response, Bard states that information available in the public domain, including the
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1 FDA MAUDE database, is not a comprehensive analysis of all instances of such
2 complications. Defendants deny the remaining allegations of Paragraph 41 of Plaintiff's
3 Complaint.

4 42. Defendants admit that there are various well-documented complications that
5 may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena
6 cava filter. Bard states that there are incidents related to the occurrence of known
7 complications associated with every manufacturer of inferior vena cava filters. By way of
8 further response, Bard states that information available in the public domain, including the
9 FDA MAUDE database, is not a comprehensive analysis of all instances of such
10 complications. Defendants deny the remaining allegations of Paragraph 42 of Plaintiff's
11 Complaint.

12 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
13 Complaint.

14 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
15 Complaint.

16 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
17 Complaint.

18 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
19 Complaint, including all sub-parts thereof.

20 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
21 Complaint.

22 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
23 Complaint.

24 49. Defendants are without knowledge or information sufficient to form a belief as
25 to the truth of the allegations regarding the trade name of any inferior vena cava filter
26 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
27 allegations of Paragraph 49 of Plaintiff's Complaint.

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1 50. Defendants are without knowledge or information sufficient to form a belief as
2 to the truth of the allegations regarding the trade name of any inferior vena cava filter
3 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
4 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
5 the trademark G2® Filter System were manufactured at that facility. Defendants further
6 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
7 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.
8 Defendants deny any remaining allegations of Paragraph 50 of Plaintiff's Complaint.

9 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
10 Complaint.

11 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
12 Complaint.

13 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
14 Complaint.

15 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's
16 Complaint.

17 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
18 Complaint.

19 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
20 Complaint.

21 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
22 Complaint.

23 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
24 Complaint.

25 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's
26 Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

60. Defendants incorporate by reference their responses to Paragraphs 1-59 of Plaintiff's Complaint as if fully set forth herein.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 61 of Plaintiff's Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 62 of Plaintiff's Complaint.

63. The allegations contained in Paragraph 63 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 63 of Plaintiff's Complaint.

64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's Complaint, including all sub-parts thereof.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of Plaintiff's Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's Complaint, including all sub-parts thereof.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's Complaint.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

71. Defendants incorporate by reference their responses to Paragraphs 1-70 of Plaintiff's Complaint as if fully set forth herein.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 72 of Plaintiff's Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's Complaint.

74. The allegations contained in Paragraph 74 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 74 of Plaintiff's Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's Complaint.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

82. Defendants incorporate by reference their responses to Paragraphs 1-81 of Plaintiff's Complaint as if fully set forth herein.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 83 of Plaintiff's Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiff's Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff's Complaint.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

90. Defendants incorporate by reference their responses to Paragraphs 1-89 of Plaintiff's Complaint as if fully set forth herein.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

96. Defendants incorporate by reference their responses to Paragraphs 1-95 of Plaintiff's Complaint as if fully set forth herein.

97. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 97 of Plaintiff's Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of Plaintiff's Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint, including all subparts thereof.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

SIXTH CAUSE OF ACTION

NEGLIGENCE MISREPRESENTATION/CONSUMER FRAUD

106. Defendants incorporate by reference their responses to Paragraphs 1-105 of Plaintiff's Complaint as if fully set forth herein.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's Complaint, including all subparts thereof.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's Complaint.

PUNITIVE DAMAGES ALLEGATIONS

117. Defendants incorporate by reference their responses to Paragraphs 1-116 of Plaintiff's Complaint as if fully set forth herein.

118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's Complaint, including all sub-parts thereof.

120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading “PRAYER FOR DAMAGES” and beginning “WHEREFORE,” Defendants deny the allegations contained in such Paragraph and sub-parts.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of negligence, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability failure to warn, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability design defect, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of strict liability manufacturing defect, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of breach of implied warranty, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Further, responding to the unnumbered Paragraph regarding Plaintiff's allegations of negligent misrepresentation/consumer fraud, Defendants deny the allegations contained in such Paragraph, including all subparts thereof. Defendants deny that Plaintiff is entitled to any relief requested in the Plaintiff's Complaint.

Defendants further deny each and every allegation not specifically admitted herein

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

1 4. If Plaintiff has been damaged, which Defendants deny, any recovery by
2 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or
3 failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her
4 alleged damages, any recovery shall not include alleged damages that could have been
5 avoided by reasonable care and diligence.

6 5. If Plaintiff has been damaged, which Defendants deny, such damages were
7 caused by the negligence or fault of Plaintiff.

8 6. If Plaintiff has been damaged, which Defendants deny, such damages were
9 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
10 not legally responsible.

11 7. The conduct of Defendants and the subject product at all times conformed with
12 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
13 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
14 part, under the doctrine of federal preemption, and granting the relief requested would
15 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
16 violation of the Supremacy Clause of the United States Constitution.

17 8. If Plaintiff has been damaged, which Defendants deny, such damages were
18 caused by unforeseeable, independent, intervening, and/or superseding events for which
19 Defendants are not legally responsible.

20 9. There was no defect in the product at issue with the result that Plaintiff is not
21 entitled to recover against Defendants in this cause.

22 10. If there were any defect in the products – and Defendants deny that there were
23 any defects – nevertheless, there was no causal connection between any alleged defect and
24 the product on the one hand and any damage to Plaintiff on the other with the result that
25 Plaintiff is not entitled to recover against Defendants in this cause.

26 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
27 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
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1 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
2 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
3 either in whole or in part, from all persons or entities whose negligence or fault proximately
4 caused or contributed to cause Plaintiff's alleged damages.

5 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
6 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
7 at issue in a manner not intended by Defendants and over which Defendants had no control.

8 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
9 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
10 possession, custody, and control of Defendants.

11 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
12 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
13 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
14 Defendants.

15 15. Plaintiff's claims for breach of implied warranty must fail because the product
16 was not used for its ordinary purpose.

17 16. Defendants neither had nor breached any alleged duty to warn with respect to
18 the product, with the result that Plaintiff is not entitled to recover in this cause.

19 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
20 warnings and instructions to learned intermediaries.

21 18. At all relevant times, herein, Plaintiff's physicians were in the position of
22 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
23 benefits of the subject product.

24 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
25 entities for whose conduct Defendants are not legally responsible and the independent
26 knowledge of these persons or entities of the risks inherent in the use of the product and other

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1 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
2 damages.

3 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
4 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
5 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
6 unknown, unknowable, or not reasonably foreseeable to Defendants.

7 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
8 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
9 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
10 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
11 damages that Plaintiff seeks to recover herein.

12 22. At all relevant times during which the device at issue was designed, developed,
13 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
14 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
15 information, and instructions, all pursuant to generally recognized prevailing industry
16 standards and state-of-the-art in existence at the time.

17 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
18 result of the alleged conduct and do not have any right, standing, or competency to maintain
19 claims for damages or other relief.

20 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
21 estoppel, and/or laches.

22 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
23 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
24 doctrines of contributory and/or comparative negligence.

25 26. In the further alternative, and only in the event that it is determined that
26 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
27 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
28

1 any other defendants, third-party defendants, or other persons, including any party immune
 2 because bankruptcy renders them immune from further litigation, as well as any party, co-
 3 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

4 27. Should Defendants be held liable to Plaintiff, which liability is specifically
 5 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
 6 from all collateral sources.

7 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
 8 against Defendants pursuant to the doctrines of *res judicata*, collateral estoppel, release of
 9 claims, and the prohibition on double recovery for the same injury.

10 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
 11 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
 12 over which Defendants had no control.

13 30. The conduct of Defendants and all activities with respect to the subject product
 14 have been and are under the supervision of the Federal Food and Drug Administration
 15 (“FDA”). Accordingly, this action, including any claims for monetary and/or injunctive relief,
 16 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

17 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
 18 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
 19 their Answer to file such further pleadings as are necessary to preserve and assert such
 20 defenses, claims, credits, offsets, or remedies.

21 32. The device at issue complied with any applicable product safety statute or
 22 administrative regulation, and therefore Plaintiff's defective design and warnings-based
 23 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
 24 comments thereto.

25 33. Plaintiff cannot show that any reasonable alternative design would have
 26 rendered the Recovery® Filter inferior vena cava filter device as alleged in Plaintiff's
 27 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,

1 nor could Defendants have known of any alternative design that may be identified by
2 Plaintiff.

3 34. The device at issue was not sold in a defective condition unreasonably
4 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
5 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
6 comparable provisions of the Restatement (Third) of Torts (Products Liability).

7 35. At all relevant times during which the device at issue was designed, developed,
8 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
9 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
10 information, and instructions, all pursuant to generally recognized prevailing industry
11 standards and state-of-the-art in existence at the time.

12 36. Defendants specifically plead all affirmative defenses under the Uniform
13 Commercial Code ("UCC") now existing or which may arise in the future, including those
14 defenses provided by UCC §§ 2-607 and 2-709.

15 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
16 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
17 Act.

18 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
19 grossly negligent, and, therefore, any award of punitive damages is barred.

20 39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory
21 providing for liability without proof of defect and proof of causation, the claims violate
22 Defendants' rights under the Constitution of the United States and analogous provisions of
23 the Pennsylvania Constitution.

24 40. Regarding Plaintiff's demand for punitive damages, Defendants specifically
25 incorporate by reference any and all standards of limitations regarding the determination
26 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No.*
27 *America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group*,

1 *Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513
2 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25,
3 2008) and their progeny as well as other similar cases under both federal and state law.

4 41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore
5 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
6 the United States of America, and similar provisions of the Pennsylvania Constitution, on
7 grounds including the following:

- 8 (a) it is a violation of the Due Process and Equal Protection Clauses of the
9 Fourteenth Amendment of the United States Constitution to impose punitive
10 damages, which are penal in nature, against a civil defendant upon the plaintiffs
11 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
12 burden of proof required in criminal cases;
- 13 (b) the procedures pursuant to which punitive damages are awarded may result in
14 the award of joint and several judgments against multiple defendants for
15 different alleged acts of wrongdoing, which infringes upon the Due Process and
16 Equal Protection Clauses of the Fourteenth Amendment of the United States
17 Constitution;
- 18 (c) the procedures to which punitive damages are awarded fail to provide a
19 reasonable limit on the amount of the award against Defendants, which thereby
20 violates the Due Process Clause of the Fourteenth Amendment of the United
21 States Constitution;
- 22 (d) the procedures pursuant to which punitive damages are awarded fail to provide
23 specific standards for the amount of the award of punitive damages which
24 thereby violates the Due Process Clause of the Fourteenth Amendment of the
25 United States Constitution;
- 26 (e) the procedures pursuant to which punitive damages are awarded result in the
27 imposition of different penalties for the same or similar acts, and thus violate

the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiff has failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

1 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
2 the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
3 against them be dismissed and that they be awarded their costs in defending this action and
4 that they be granted such other and further relief as the Court deems just and appropriate.

5 This 27th day of October, 2015.

6 s/Richard B. North, Jr.

7 Richard B. North, Jr.

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25 **Attorney for Defendants C. R. Bard, Inc. and**
26 **Bard Peripheral Vascular, Inc.**

27

28

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 27, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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